



FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1134CON		SERIAL NO.: 10/827,623							
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)				APPLICANT(S): Benjamin OSHLACK et al.									
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	BR	Miakowski et al., "Inhibition of Spinal Opioid Analgesia by Supraspinal Administration of Selective Opioid Antagonists", Brain Research (1992), 30:263-274.											
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<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	DM	Alvarez-Fuentes, et al. "Effectiveness of Repeated Administration of a New Ora Naltrexone Controlled-Release System in Morphine Analgesia"; J. Pharm Pharmacol (2001), 53:1201-1205.					
	DN	Alvarez-Fuentes, et al., "Preclinical Study of an Oral Controlled Release Naltrexone Complex in Mice"; J. Pharm Pharmacol (2000), 52:659-663.					
	DO	Archer, Sydney; "Historical Perspective on the Chemistry and Development of Naltrexone"; Naltrexone Research Monograph 28 (1980) p. 3-9.					
	DP	Baum et al., "The Impact of the Addition of Naloxone on the Use and Abuse of Pentazocine"; Public Health Reports (1987) Vol. 102, No. 4 p. 426-429.					
	DQ	Rapaka et al., "Discovery of Novel Opioid Medications"; NIDA Research Monograph 147 (1995) p. 55-83.					
	DR	Bloom et al., "Clinical Studies with Naloxone/Methadone in a Ratio of 1:20"; 5 <sup>th</sup> National Conference on Methadone Treatment (1973) Vol 2, p. 1342-1349.					
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	EM	Briscoe et al., "Methodocinnamox: Time Course of Changes in Alfenanil-Reinforced Rhesus Monkeys"; Psychopharmacology (2000) 148:393-399.					
	EN	Abstract of Bromm, et al., "A Sensitive Method to Evaluate Effects of Analgesics in Man"; Meth and Find Exptl Clin Pharmacol 5 (8) (1983) p. 545-551.					
	EO	Bullingham et al., "Clinical Pharmacokinetics of Narcotic Agonist-Antagonist Drugs"; Clinical Pharm (1983) 8: 332-343.					
	EP	Calimlim, et al. "Effect of Naloxone on the Analgesic Activity of Methadone in a 1:10 Oral Combination"; Clin Pharmacol and There (1974) Vol. 15; No. 6 pp.556-564.					
	EQ	Caruso et al., "Methadone and Naloxone in Combination (Naldone®) for the Treatment if Heroin Addicts"; Bristol Laboratories, pp.1336-1341F.					
	ER	Cherny, Nathan I., "Opioid Analgesics"; Drugs (1996) May:51 (5) pp. 713-737.					
	ES	Chiang, et al. "Clinical Evaluation of a Naltrexone Sustained-Release Preparation"; Drug and Alcohol Dependence (1985) 16, pp.1-8.					
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	FL	Chiang et al., "Kinetics of a Naltrexone Sustained-Release Preparation"; Clin Pharmacol Thera (1984) Vol 36 No. 5, pp.704-708.					
	FM	Comer et al., "Depot Naltrexone: Long-lasting Antagonism of the Effects Of Heroin un Humans"; Psychopharmacology (2002) 159, pp.351-360.					
	FN	Crabtree et al., "Review of Naltrexone, a long-acting Opiate Antagonist"; Clinical Pharmacy, Vol. 3 (1984) pp.273-280.					
	FO	Crain et al., "Antagonists of Excitatory Opioid Receptor Functions Enhance Morphine's Analgesic Potency and Attenuate Opioid Tolerance/dependence liability"; Dept. of Neuroscience, Albert Einstein College of Medicine Pain 82 (1999)pp.1-11.					
	FP	Crain et al., "Antagonists of Excitatory Opioid Receptor Functions Enhance Morphine's Analgesic Potency and Attenuate Opioid Tolerance/dependence liability"; Dept. of Neuroscience, Albert Einstein College of Medicine Pain 84 (2000) pp.121-131.					
	FQ	Fink et al., "naloxone in Heroin Dependence"; Clin Pharm and Thera. Vol 9, No. 5;pp.568-577.					
	FR	Fishman et al., "Disposition of Naloxone-7,8- <sup>3</sup> H in Normal & Narcotic Dependent Men"; J. Pharm. And Exper. Thera (1973)Vol 10 No. 2;pp.575-580.					
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	GI	Fraser, Albert D., et al., "Clinical Toxicology of Drugs Used in the Treatment of Opiate Dependency"; Clinical Toxicology I (1990) Vol 10, No. 2; pp.375-386.					
	GL	Freye et al., "Effects of Tramadol and Tilidine/Naloxone on Oral-Caecal Transit & Pupillary light Reflex"; Arzneim-Forsch/Drug Res. 50(I)(2000)pp. 24-30.					
	GK	Fudala, et al., "Effects of Buprenorphine asnd Naloxone in Morphine-Stabilized Opioid Addicts"; Drug and Alcohol Dependence 50 (1998) pp. 1-8.					
	GL	Fudala et al., "Human Pharmacology and Abuse Potential Of Nalmefene"; Clin Pharm and Thera (1991) Vol 49, 3, pp. 300-306.					
	GM	Gal et al., "Prolonged Blockade of Opioid Effect with Oral Nalmefene"; Clin Pharm and Thera (1986) pp. 537-542.					
	GN	Gerra et al., "Clonidine and Opiate Receptor Antagonists in the Treatment of Heroin Addiction"; J. Substance Abuse Treatment (1995) Vol 12, 1, pp. 35-41.					
	GO	Ghodse, et al., "Opioid analgesics and Narcotic Antagonists"; Side Effects of Drugs (2000) Annual 23, chpt 8 pp. 96-113.					
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<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	HI	Glatt, William, M.D. FACP, "A New Method for Detoxifying Opioid-Dependent Patients"; J. Substance Abuse Treatment (1999) Vol.17, No.3, pp. 193-197					
	HJ	Gold, et al. "Rapid Opioid Detoxification During General Anesthesia"; Anesthesiology (1999) Vol 91, No 6, pp. 1639-1647.					
	HK	Greenwald, et al., "Comparative Clinical Pharmacology of Short-Acting $\mu$ Opioids in Drug Abusers"; J. Pharm and Exper Thera (1996) Vol 277, No 3, pp. 1228-1236.					
	HC	Gupta, et al., "Morphine Combined with Doxapram or Naloxone"; Anesthesia (1974) Vol 29, pp. 33-39.					
	HM	Richter et al., "Clinical Investigation on the Development of Dependence during Oral Therapy with Tramadol"; Arzneim-Forsch/Drug Res. 35 (No II)(1985)pp. 1742-1744.					
	HI	Rosen et al., "The effect of Lamotrigine on Naloxone-precipitated Opiate withdrawal"; Drug and Alcohol Dependence (1998) Vol 52, pp. 173-176.					
	HO	Rosen et al., "A Pilot Study of Dextromethorphan in Naloxone-Precipitated Opiate Withdrawal"; European J. of Pharm. (1996) Vol 307, pp. 251-257.					
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<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	IJ	Schuh et al., "Buprenorphine, Morphine and Naloxone Effects during Ascending Morphine Maintenance in Humans"; J. Pharm and Exper Thera (1996) Vol 278, 2, pp. 836-846.					
	IK	Schuh et al., "Onset, Magnitude and Duration of Opioid Blockade Produced by Buprenorphine and Naltrexone in Humans"; Psychopharmacology (1999) Vol 145, pp. 162-174.					
	IL	Stevens et al., "Nonspecific Excitatory Effects of Morphine: Reverse-Order Precipitated Withdrawal and Dose-Dose Interactions"; Psychopharmacology (1981) Vol 75, pp. 210-211.					
	IM	Stine et al., "Reduction of Opiate Withdrawal-like Symptoms by Cocaine Abuse during Methadone and Buprenorphine Maintenance"; Am. J. Drug and Alcohol Abuse (1994) Vol 20, 4, pp. 445-458.					
	IN	Stine et al., "Use of Drug Combinations in Treatment of Opioid Withdrawal"; J. Clinical Psych. (1992) Vol 12, No 3, pp. 203-209.					
	IO	Stoller et al., "Effects of buprenorphine/naloxone in opioid-dependent humans" Psychopharmacology (2001) Vol 154, pp. 230-242.					
	IP	Strain et al., "Acute Effects of Buprenorphine, hydromorphone and naloxone in methadone-maintained volunteers"; J. Pharm and Exper Thera (1992) Vol 261, No 3, pp. 985-993.					
	IQ	Strain et al., "Effects of buprenorphine versus buprenorphine/naloxone tablets in non-dependent opioid abusers"; Psychopharmacology (2000) Vol 148, pp. 374-383.					
	IR	Strain et al., "Precipitated Withdrawal by Pentazocine in Methadone-Maintained Volunteers"; J. Pharm and Exper Thera (1993) Vol 267, No 2, pp. 624-634.					
	IS	Tai, et al., "Naltrexone: An Antagonist Therapy for Heroin Addiction"; NIDA (1997) 5 pages					
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	JI	Umbrecht et al., "Naltrexone shortened opioid detoxification with buprenorphine"; Drug and Alcohol Dependence (1999) Vol 56 pp. 181-190								
	JK	Vaccarino et al., "Enogenous Opiates: 1999"; Peptides 21 (2000) pp. 1975-2034.								
	JL	Wang et al., "Inverse Agonists and neutral antagonists at $\mu$ opioid receptor (MOR): possible role of basal receptor signaling in narcotic dependence"; J. Neurochemistry (2001) Vol 77, pp. 1590-1600.								
	JM	Way et al., "Responsivity to Naloxone during Morphine Dependence"; Annals New York Academy of Sciences, pp. 252-261.								
	JN	Weinberg et al., "Sublingual absorption of selected opioid analgesics"; Clin Pharm Thera (1988) Vol 44, No 3, pp. 335-342.								
	JO	Wells, et al., "In vivo Pharmacological Characterization of SoRI 9409, a Nonpeptidic Opioid $\mu$ -Agonist/ $\delta$ -Antagonist that Produces Limited Antinociceptive Tolerance and Attenuates Morphine Physical Dependence"; J. Pharm and Exper Thera (2001) Vol 297, No 2, pp. 597-605								
	JP	Wodak, Alex, "Drug Treatment for Opioid Dependence"; Australian Prescriber (2001) Vol 24, No 1, pp. 4-6.								
	JQ	Wright et al., "Acute physical dependence in Humans; repeated naloxone-precipitated withdrawal after a single-dose of methadone"; Drug and Alcohol Dependence (1991) Vol 27, pp. 139-148.								
	JR	Zhu et al., "Naltrexone-precipitated morphine withdrawal in infant rat is attenuated by acute administration if NOS inhibitors but not NMDA receptor antagonists"; Psychopharmacology (2000) Vol 150, pp. 325-336.								
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	KL	Han et al., "Mucocoadhesive buccal disks for novel nalbuphine prodrug controlled delivery; effect of formulation variable on drug release and mucocoadhesive performance"; International J. Pharm (1999) Vol 177, pp. 201-209.					
	KJ	Handal et al., "Naloxone"; Annals of Emergency Medicine (1983) Vol 12:7, pp. 438-445.					
	KK	Harris et al., "Buprenorphine and Naloxone co-administration in opiate dependent patients stabilized on sublingual buprenorphine"; Drug and Alcohol Dependence (2000) Vol 61, pp. 85-94.					
	KL	Hawkes et al., "Effect of enteric-release formulation of naloxone on intestinal transit in volunteers taking codeine"; Aliment Pharm Ther (2001) Vol 15, pp. 625-630.					
	KM	Högger et al., "Comparison of tilidine/naloxone, tramadol and bromfenac in experimental pain: a double-blind randomized crossover study in healthy human volunteers"; International J. Clin Pharm and Thera (1999) Vol 37, No 8, pp. 377-385					
	KN	Budd, Keith, "Clinical Use of Opioid Antagonists"; Bailliere's Clinical Anesthesiology (1987) Vol 1, No 4, pp. 993-1011.					
	KO	Crain et al., "Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence					
	KE	Howes et al., "The Pharmacology of TR5109, a new Narcotic Agonist/Antagonist Analgesic"; NIDA Research (1979) pp. 99-105.					
	KQ	Leeling et al., "Disposition and metabolism of codorphone in the rat, dog, and man"; Drug Metabolism and Disposition (1982) Vol 10, No 6, pp 649-653.					
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	LK	Amass et al., "Efficacy of daily and alternate-day dosing regimens with the combination buprenorphine-naloxone tablet"; Drug and Alcohol Dependence (2000) Vol 58, pp. 143-152.									
	LJ	Hassain et al., "Buccal and oral bioavailability of naloxone and naltrexone in rats"; (1987) Vol 36, pp. 127-130.									
	LK	Jasinski et al., "The human pharmacology and abuse potential of N-allylnoroxymorphone naloxone"; J. Pharm and Exper Thera (1967) Vol 157, No 2, pp. 420-426.									
	LM	Jones et al., "Nalmefene: blockade of intravenous morphine challenge effects in opioid abusing humans"; Drug and Alcohol Dependence (2000) Vol 60, pp. 29-37.									
	LN	Kanof et al., "Clinical Characteristics of Naloxone-Precipitated Withdrawal in Human Opioid-Dependent Subjects"; J Pharma and Exper Thera (1992) Vol 260, No. 1, pp. 355-363.									
	LO	King et al., "Naltrexone Biotransformation and Incidence of Subjective Side Effects: A Preliminary Study"; Alcoholism: Clin and Exper Res (1997) Vol 21, No 5, pp. 906-909.									
	LP	Kogan et al., "Estimation of the Systemic Availability and Other Pharmacokinetic Parameters of Naltrexone in Man after Acute and Chronic Oral Administration"; Res. Comm. In Chem. Path. And Pharm (1977) Vol 18, No. 1, pp 29-34.									
	LQ	Kosten, Thomas R., M.D., "Buprenorphine for Benzodiazepine-Abusing Heroin Addicts"; Amer J of Psychiatry (1994) Vol 1, p 151.									
	LP	Kosten et al., "Opioid antagonist challenges in buprenorphine maintained patients"; Drug and Alcohol Dependence (1990) Vol 25, OO. 73-78.									
	LS	Kurland et al., "Naloxone and the Narcotic Abuser: A Controlled Study of Partial Blockade"; Inter. J. of the Addictions (1974) Vol 9, No 5, pp. 663-672.									
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	MH	Lee et al., "Nalbuphine Coadministered with Morphine Prevents Tolerance and Dependence"; Anesth Analg (1997) Vol 84, pp.810-815					
	MI	Lehman, et al., "Influence of Naloxone on the Postoperative Analgesic and Respiratory effects of Buprenorphine"; Eur. J. Clin Pharm (1988) Vol 34, pp. 343-352.					
	MJ	Levine et al., "Potentiation of Pentazocine Analgesia by Low-dose Naloxone"; J Clin Invest (1988) Vol 82, pp. 1574-1577.					
	MK	Loimer et al., "Combined Naloxone/Methadone Preparations for Opiate Substitution Therapy"; J. of Substance Abuse Treatment (1991) Vol 8, pp. 157-160.					
	ML	Martin et al. "Bioavailability Investigation of a New Tilidine/Naloxone Liquid Formulation Compared to a Reference Formulation"; Arzneim-Forsch./Drug Res. (1999) Vol 49, pp. 599-607.					
	MM	Martin et al., "Demonstration of Tolerance to and Physical Dependence on N-allylnormorphine (Nalorphine)"; J. Of Pharm and Exper Thera (1965) Vol 150, No 3. Pp. 437-442.					
	MN	Mendelson et al., "Buprenorphine and naloxone combinations: the effects of three dose ratios in morphine stabilized, opiate-dependent volunteers"; Psychopharmacology (1999) Vol 141, pp. 37-46.					
	MO	Mendelson et al., "Buprenorphine and naloxone Interactions in Methadone Maintenance Patients"; Society of Biological Psychiatry (1997) Vol 41, pp. 1095-1101.					
	MP	Nutt et al., "Methadone-naloxone mixture for use in methadone maintenance programs"; Clin Pharm and Ther. Vol 15, No 2., pp 156-166					
EXAMINER				DATE CONSIDERED			
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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			ATTY. DOCKET NO.: 200.1134CON		SERIAL NO.: 10/827,623				
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)					APPLICANT(S): Benjamin OSHLACK et al.						
					FILING DATE: December 29, 2003		GROUP: 1614				
<b>U.S. PATENT DOCUMENTS</b>											
*EXAMINER INITIAL		DOCUMENT NUMBER				DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	NA										
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		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
										YES	NO
	NF										
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>											
	NG	Parwatikar et al., "Methadone-naloxone in combination for the Treatment of Heroin Addicts"; Clin. Pharm and Thera, Vol 14, No. 6, pp 941-948.									
	NH	Parwartikar et al., "Naloxone-Methadone Combination for the Treatment of Opiate Dependence"; Missouri Institute of Psychiatry, pp. 1350-1354.									
	NI	Pitts et al., "Antinociceptive and Response Rate-Altering Effects of <i>Kappa</i> Opioid Agonists, Spiradoline, Enadoline and U69,593, Alone and in Combination with Opioid Antagonists in Squirrel Monkeys"; J of Pharm and Exper Thera (1994) Vol 271, No 3, pp. 1501-1508.									
	NJ	Preston et al., "Buprenorphine and Naloxone alone and in combination in Opioid-dependant Humans"; Psychopharmacology (1988), Vol 94, pp. 484-490.									
	NK	Preston et al., "Differential Naltrexone Antagonism of Hydromorphone and Pentazocine Effects in Human Volunteers"; J of Pharm and Exper Thera (1993) Vol 264, No 2 pp. 813-823.									
	NL	Preston et al., "Effects of Sublingually given naloxone in Opioid -dependant human volunteers"; Drug and Alcohol Dependence (1990) Vol 25, pp. 27-34.									
	NM	Bigelow et al., "Abuse Liability and Assessment of Buprenorphine-Naloxone Combinations"; Dept of Psychiatry and Behavioral Sciences, The Johns Hopkins University School of Medicine, pp. 145-149.									
	NN	Wikler et al., "N-Allylnormorphine: Effects of single dose and Precipitation of Acute "Abstinence Syndromes" during addiction to morphine, methadone or heroin in man (post addicts)"; N-Allylnormorphine During Narcoctic Addiction (1953) pp. 8-20.									
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	OF						
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	OG	Zaks et al., "Naloxone Treatment of Opiate Dependence"; JAMA (1971) Vol 215, No 13, pp. 2108-2110.					
	OH	Barton, et al., "Intranasal Administration of Naloxone by Paramedics"; Prehospital Emergency Care (2002) Vol 6, No 1, pp. 54-58.					
	OI	Blachly, Paul, H., M.D., "Naloxone in Opiate Addiction"; Current Psychiatric Therapies (1976) pp. 209-213.					
	OJ	Bashaw et al., "Relative bioavailability of controlled-release oral morphine sulfate during naltrexone blockade"; Inter J of Clin Pharm and Thera (1995) Vol 33, No 9, 524-529.					
	OJ	Jasinski, D.R., "Assessment of the Abuse Potential of Morphinelike Drugs (Methods Used in Man)"; Drug Addiction (1977) pp. 197-258.					
	OL	Johnson et al., "Buprenorphine and Naloxone for Heroin Dependence"; Substance Use Disorders (2000) pp. 519-526.					
	OM	Strain et al., "Opioid antagonist effects of dezocine in opioid-dependent humans"; Clin Pharm and Thera (1996) Vol 60, No 2, pp. 206-217.					
	ON	Preston et al., "Abuse liability and studies of opioid agonist-antagonists in humans"; Drug and Alcohol Dependence (1991) vol 28, pp. 49-82.					
	OO	Brennscheidt et al., "Pharmacokinetics of Nortilidine and Naloxone after Administration of Tilidine/Naloxone Solution or Tilidine/Naloxone Sustained Release Tablets"; Arznei-Forsch/Drug Res. (2000) Vol 50, pp. 1015-1022.					
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	RP						
	RQ	Physician's Desk Reference (2001) see Revia, pp. 1146-1149 and Oxycontin, pp. 2697-2701					
	RR						
	RS						
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EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
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JR	BA	3	9	1	6	8	8	9	11/04/1975	Russell	128	145.8		
JR	BB	3	9	6	5	2	5	6	06/22/1976	Leslie	424	22		
JR	BC	3	9	6	6	9	4	0	6/76	Pachter et al.	424	260		
JR	BD	4	1	7	6	1	8	6	11/79	Goldberg	424	260		
JR	BE	4	2	3	7	1	4	0	12/02/1980	Dudzinski	424	260		
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JR	BF	9	7	3	3	5	6	6	9/97	WO	A61K	9/20		
JR	BG	9	8	3	5	6	7	9	8/98	WO	A61K	31/485		
JR	BH	9	9	3	2	1	2	0	7/99	WO	A61K	31/485		
JR	BI	0	0	0	1	3	7	7	01/13/2000	WO	A61K	31/00		
JR	BJ	8	7	0	1	2	8	2	03/12/1987	WO	A61K	31/485		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
JR	BK	Chih-Cheng Chien, et al., "Sigma Antagonists Potentiate Opioid Analgesia in Rats", Neuroscience Letters 190 (1995), 137-139.												
JR	BL	Crain et al., "Ultra-Low Concentrations of Naloxone Selectively Antagonize Excitatory Effects of Morphine on Sensory Neurons, Thereby Increasing Its Antinociceptive Potency and Attenuating Tolerance/Dependence During Chronic Cotreatment," Proc. Natl. Acad. Sci. USA (1995) 92:10540-10544.												
JR	BN	Hanson, Analgesic, Antipyretic and Anti-Inflammatory Drugs in Remington's Science and Practice of Pharmacy (1995), 2:1207.												
JR	BO	Tatwin NX, Physician's Desk Reference 48th Ed. (1994) Montvale, NJ 2120-2121.												
JR	BP	Foss et al., "Dose related Antagonism of the Emetic Effect of Morphine by Methylnaltrexone in Dogs", J. Clin Pharmacol (1993), 33:747-751												
JR	BQ	Holmes et al., "Inhibiting Spinal Dynorphin A Component Enhances Intrathecal Morphine Antinociception in Mice", Anesth. Analg. (1993), 77:1166-73.												
JR	BR	Mikowski et al., "Inhibition of Spinal Opioid Analgesia by Supraspinal Administration of Selective Opioid Antagonists", Brain Research (1992), 50:263-274.												
EXAMINER Jeffrey E. Russell										DATE CONSIDERED January 25, 2005				
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		4	5	7	3	9	9	5					YES	NO
<i>BL</i>	DA	4	5	7	3	9	9	5	3/86	Chen et al.	604	896		
<i>BL</i>	DB	4	5	9	2	8	3	5	4/86	Lewis et al.	514	282		
<i>BL</i>	DC	4	6	0	8	3	7	5	8/86	Pasternak	514	282		
<i>BL</i>	DD	4	6	9	1	4	9	2	4/87	Lewis et al.	514	282		
<i>BL</i>	DE	4	7	1	9	2	1	5	1/88	Goldberg	514	282		
<i>BL</i>	DF	4	7	3	0	0	4	8	3/88	Portoghese et al.	546	45		
<i>BL</i>	DG	4	7	6	0	0	6	9	7/88	Rzeszutarski et al.	514	282		
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<i>BL</i>	DI	0	9	1	3	1	5	2	6/99	EP	A61K	31/485		
<i>BL</i>	DJ	0	6	4	7	4	4	8	4/85	EP	A61K	31/485		
<i>BL</i>	DK	0	3	5	2	3	6	1	1/90	EP	A61K	31/485		
<i>BL</i>	DL	0	2	0	5	2	8	2	12/86	EP	A61K	9/22		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
<i>BL</i>	DM	Alvarez-Fuentes, et al. "Effectiveness of Repeated Administration of a New Oral Naltrexone Controlled-Release System in Morphine Analgesia"; J. Pharm Pharmacol (2001), 53:1201-1205.												
<i>BL</i>	DN	Alvarez-Fuentes, et al., "Preclinical Study of an Oral Controlled Release Naltrexone Complex in Mice"; J. Pharm Pharmacol (2000), 52:659-663.												
<i>BL</i>	DO	Archer, Sydney, "Historical Perspective on the Chemistry and Development of Naltrexone", Naltrexone Research Monograph 28 (1980) p. 3-9												
<i>BL</i>	DP	Baum et al., "The Impact of the Addition of Naloxone on the Use and Abuse of Pentazocine"; Public Health Reports (1987) Vol. 102, No. 4, p. 426-429.												
<i>BL</i>	DQ	Rapaka et al., "Discovery of Novel Opioid Medications"; NIDA Research Monograph 147 (1995) p. 53-63.												
<i>BL</i>	DR	Bloom et al., "Clinical Studies with Naloxone/Metadone in a Ratio of 1:20"; 5th National Conference on Methadone Treatment (1973) Vol 2, p. 1342-1349.												
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10747,865

## LIST OF PRIOR ART CITED BY APPLICANT

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APPLICANT(S):  
Benjamin OSHLACK et al.FILING DATE:  
December 29, 2003GROUP:  
1614

## U.S. PATENT DOCUMENTS

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JR	EA	4	7	6	9	3	7	2	9/88	Kreek et al.	514	282	
JR	EB	4	7	8	5	0	0	0	11/88	Kreek et al.	514	282	
JR	EC	4	8	0	3	2	0	8	2/89	Pasternak	514	282	
JR	ED	4	8	0	6	3	4	1	2/89	Chien et al.	424	448	
JR	EE	4	8	0	6	5	4	3	2/89	Choi	514	464	
JR	EF	4	8	0	6	5	5	8	2/89	Wuest et al.	514	381	
JR	EG	4	8	2	8	8	3	6	05/09/1989	Elger et al.	424	419	

## FOREIGN PATENT DOCUMENTS

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JR	EH	0	1	9	3	3	5	5	09/03/1986	EP (A3)	A61K	31/615		
JR	EI	0	3	1	9	2	4	3	06/07/1989	EP (A1)	A61K	31/485		
JR	EJ	0	3	1	9	2	4	3	11/07/1990	EP (B1)	A61K	31/485		
JR	EK	19	6	5	1	5	5	1	6/98	DE	A61K	31/485		
JR	EL	29	7	1	9	7	0	4	2/97	DE	A61K	31/485	x	

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

✓	EM	Briscoe et al., "Methoclopramide: Time Course of Changes in Aflentanil-Reinforced Rhesus Monkeys", Psychopharmacology (2000) 148:393-399.
✓	EN	Abstract of Bromberg et al., "A Sensitive Method to Evaluate Effects of Analgesics in Man", Meth and Find Exp Clin Pharmacol 5 (8) (1983) p. 545-551.
✓	EO	Bullingham et al., "Clinical Pharmacokinetics of Narcotic Agonist-Antagonist Drugs", Clinical Pharm (1983) 8: 332-343.
✓	EP	Calimlin et al. "Effect of Naloxone on the Analgesic Activity of Methadone in a 1:10 Oral Combination", Clin Pharmacol and Ther (1974) Vol. 15; No. 6 pp.556-564.
✓	EQ	Caruso et al., "Methadone and Naloxone in Combination (Naloxone) for the Treatment of Heroin Addicts", Bristol Laboratories, pp.1336-1341F.
✓	ER	Cherny, Nathan I., "Opioid Analgesics", Drugs (1996) May;51 (5) pp. 713-737.
✓	ES	Chiang, et al. "Clinical Evaluation of a Naloxone Sustained-Release Preparation", Drug and Alcohol Dependence (1985) 16, pp.1-8.

EXAMINER

Jeffrey E. Russell

DATE CONSIDERED

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JA	FA	4	8	3	4	9	6	5	05/30/1989	Martani et al.	424	488			
JA	FB	4	8	3	4	9	8	4	05/30/1989	Goldie et al.	424	488			
JA	FC	4	8	3	4	9	8	5	05/30/1989	Elger et al.	424	488			
JA	FD	4	8	4	4	9	0	7	07/04/1989	Elger et al.	424	465			
JA	FE	4	8	4	4	9	0	9	07/04/1989	Goldie et al.	424	480			
JA	FF	4	8	4	4	9	1	0	07/04/1989	Leslie et al.	424	494			
JA	FG	4	8	6	1	5	9	8	8/89	Oshlak et al.	424	468			
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JA	FI	2	2	2	2	0	3	9	11/72	DE	A61K	27/00			
JA	FJ	9	8	2	5	6	1	3	06/18/98	WO	A61K	31/485	abstract		
JA	FK	0	0	3	8	6	4	9	07/06/00	WO	A61K	9/00	abstract		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>															
<input checked="" type="checkbox"/>	FL	Chiang et al., "Kinetics of a Naltrexone Sustained-Release Preparation", Clin Pharmacol Ther (1984) Vol 36 No. 5, pp.704-708.													
<input checked="" type="checkbox"/>	FM	Gomer et al., "Depot Naltrexone: Long-lasting Antagonism of the Effects Of Heroin in Humans", Psychopharmacology (2002) 159, pp.354-360.													
<input checked="" type="checkbox"/>	FN	Crabtree et al., "Review of Naltrexone, a long-acting Opiate Antagonist", Clinical Pharmacy, Vol. 3 (1984) pp.273-280.													
<input checked="" type="checkbox"/>	FO	Crain et al., "Antagonists of Excitatory Opioid Receptor Functions Enhance Morphine's Analgesic Potency and Attenuate Opioid Tolerance/dependence liability", Dept. of Neuroscience, Albert Einstein College of Medicine Pain 82 (1999) pp.1-11.													
<input checked="" type="checkbox"/>	FP	Crain et al., "Antagonists of Excitatory Opioid Receptor Functions Enhance Morphine's Analgesic Potency and Attenuate Opioid Tolerance/dependence liability", Dept. of Neuroscience, Albert Einstein College of Medicine Pain 84 (2000) pp.121-131.													
<input checked="" type="checkbox"/>	FQ	Fink et al., "naltrexone in Heroin Dependence", Clin Pharm and Thera. Vol 9, No. 5, pp.568-577.													
<input checked="" type="checkbox"/>	FR	Fishman et al., "Disposition of Naltrexone-7,8- <sup>3</sup> H in Normal & Narcotic Dependent Men", J. Pharm. And Exper. Thera (1973) Vol 10 No. 2, pp.575-588.													
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JR	GA 4 8 6 1 7 8 1	8/89	Goldberg	514	282		
JR	GB 8 8 6 7 9 8 5	09/19/1989	Heafield et al.	424	461		
JR	GC 4 8 7 3 0 7 6	10/89	Fishman et al.	412	10		
JR	GD 4 8 8 2 3 3 5	11/89	Sinclair	514	282		
JR	GE 4 8 8 8 8 6 0	12/89	Rzeszotarski et al.	514	282		
JR	GF 4 9 3 5 4 2 8	6/90	Lewis	514	282		
JR	GG 4 9 4 0 5 8 7	07/10/1990	Jenkins et al.	424	480		
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JR	CH 00 1 5 8 4 7 7	8/18/01	WO	A61P		abstract	
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
/	GI	Fraser, Albert D., et al., "Clinical Toxicology of Drugs Used in the Treatment of Opiate Dependency"; Clinical Toxicology 1 (1990) Vol 10, No. 2; pp.375-386.					
/	GJ	Freye et al., "Effects of Tramadol and Tildine/Naloxone on Oral-Caecal Transit & Pupillary light Reflex"; Arzneim-Forsch/Drug Res. 50(1)(2000)pp. 24-30.					
/	GK	Fudala, et al., "Effects of Buprenorphine and Naloxone in Morphine-Stabilized Opioid Addicts"; Drug and Alcohol Dependence 50 (1998) pp. 1-8.					
/	GL	Fudala et al., "Human Pharmacology and Abuse Potential Of Nalmefene"; Clin Pharm and Thera (1991) Vol 49, 3, pp. 300-306.					
/	GM	Gai et al., "Prolonged Blockade of Opioid Effect with Oral Nalmefene"; Clin Pharm and Thera (1986) pp. 637-642.					
/	GN	Gerra et al., "Clonidine and Opiate Receptor Antagonists in the Treatment of Heroin Addiction"; J. Substance Abuse Treatment (1995) Vol 12, 1, pp. 35-41.					
/	GO	Ghodse, et al., "Opioid analgesics and Narcotic Antagonists"; Side Effects of Drugs (2000) Annual 23, chpt 8 pp. 96-113.					
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Benjamin OSHLACK et al.FILING DATE:  
December 29, 2003GROUP:  
1614

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
JN	HA	4	2	0	0	0	9	8	04/29/1980	Ayer, et al.	128	260	
JN	HB	4	9	7	0	0	7	5	11/13/1990	Oshlak	424	451	
JN	HC	4	9	8	7	1	3	6	01/22/1991	Kreek et al.	514	282	
JN	HD	4	9	9	0	3	4	1	02/05/1991	Goldie et al.	424	484	
JN	HE	5	0	7	1	6	4	6	12/10/1991	Malkowska et al.	424	497	
JN	HF	5	0	7	5	3	4	1	12/91	Mendelson et al.	514	282	
JN	HG	5	0	8	6	0	5	8	2/92	Sinclair et al.	514	282	

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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
JN	HH	00	1	8	5	1	5	0	11/15/01	WO	A61K	31/00		

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

✓	HI	Chau, William, M.D. FACP, "A New Method for Detoxifying Opioid-Dependent Patients"; J. Substance Abuse Treatment (1999) Vol.17, No.3, pp. 193-197
✓	HJ	Gold, et al. "Rapid Opioid Detoxification During General Anesthesia"; Anesthesiology (1999) Vol 91, No 6, pp. 1639-1647.
✓	HK	Greenwald, et al. "Comparative Clinical Pharmacology of Short Acting $\mu$ -Opioids in Drug Abusers"; J. Pharm and Exper Thera (1996) Vol 277, No 3, pp. 1228-1236.
✓	HL	Gupta, et al., "Morphine Combined with Doxapram or Naloxone"; Anesthesia (1974) Vol 29, pp. 33-39.
✓	HM	Richter et al., "Clinical Investigation on the Development of Dependence during Oral Therapy with Tramadol"; Arzneim-Forsch/Drugs Res. 35 (No II)(1985)pp. 1742-1744.
✓	HN	Rosen et al., "The effect of Lamotrigine on Naloxone-precipitated Opiate withdrawal"; Drug and Alcohol Dependence (1998) Vol 52, pp. 173-176.
✓	HO	Rosen et al., "A Pilot Study of Dextromethorphan in Naloxone-Precipitated Opiate Withdrawal"; European J. of Pharm. (1996) Vol 307, pp. 251-257.

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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1134CON		SERIAL NO.: 10/747,865	
<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (Use several sheets if necessary)				APPLICANT(S): Benjamin OSHLACK et al.			
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*EXAMINER INITIAL	ID	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
JR	IA	5 0 9 1 1 8 9	02/25/1992	Heafield et al.	424	457	
JR	IB	5 0 9 6 2 1 5	3/92	Sinclair	424	449	
JR	IC	5 1 0 2 8 8 7	4/92	Goldberg	514	282	
JR	ID	4 1 6 0 0 2 0	07/03/1979	Ayer, et al.	424	15	
JR	IE	5 1 4 9 5 3 8	9/92	Granger et al.	424	449	
JR	IF	5 2 1 5 7 5 8	06/01/1993	Krishnamurthy	424	488	
JR	IG	5 2 2 5 4 4 0	7/93	London et al.	514	535	
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
JR	IH	00 0 6 7 7 3 9	11/16/00	WO	A61K	31/00	
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
U	✓	Schuh et al., "Buprenorphine, Morphine and Naloxone Effects during Ascending Morphine Maintenance in Humans"; J. Pharm and Exper Thera (1996) Vol 278, 2, pp. 836-846.					
IK	✓	Schuh et al., "Onset, Magnitude and Duration of Opioid Blockade Produced by Buprenorphine and Naltrexone in Humans"; Psychopharmacology (1999) Vol 145, pp. 162-174.					
IL	✓	Stevens et al., "Nonspecific Excitatory Effects of Morphine: Reverse-Order Precipitated Withdrawal and Dose-Dose Interactions"; Psychopharmacology (1981) Vol 75, pp. 210-211.					
IM	✓	Stine et al., "Reduction of Opiate Withdrawal-like Symptoms by Cocaine Abuse during Methadone and Buprenorphine Maintenance"; Am. J. Drug and Alcohol Abuse (1994) Vol 20, 4, pp. 445-458.					
IN	✓	Stine et al., "Use of Drug Combinations in Treatment of Opioid Withdrawal"; J. Clinical Psych. (1992) Vol 12, No 3, pp. 203-209.					
IO	✓	Stoller et al., "Effects of buprenorphine/naloxone in opioid-dependent humans" Psychopharmacology (2001) Vol 154, pp. 230-242.					
IP	✓	Strain et al., "Acute Effects of Buprenorphine, hydromorphone and naloxone in methadone-maintained volunteers"; J. Pharm and Exper Thera (1992) Vol 261, No 3, pp. 985-993.					
IQ	✓	Strain et al., "Effects of buprenorphine versus buprenorphine/naloxone tablets in non-dependent opioid abusers"; Psychopharmacology (2000) Vol 148, pp. 374-383.					
IR	✓	Strain et al., "Precipitated Withdrawal by Pentazocine in Methadone-Maintained Volunteers"; J. Pharm and Exper Thera (1993) Vol 267, No 2, pp. 624-634.					
IS	✓	Tai, et al., "Naltrexone: An Antagonist Therapy for Heroin Addiction"; NIDA (1997) 5 pages					
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JN	JA	5	2	2	6	3	3	1	07/13/1993	Thompson et al.	73	865.9	
JN	JB	5	2	3	6	7	1	4	8/93	Lee et al.	424	449	
JN	JC	5	2	5	6	6	6	9	10/93	Askanazi et al.	514	282	
JN	JD	5	2	6	6	3	3	1	11/30/1993	Oshlak et al.	424	468	
JN	JE	5	2	7	3	7	6	0	12/93	Oshlak et al.	424	486	
JN	JF	5	2	8	6	4	9	3	02/15/1994	Oshlak et al.	424	468	
JN	JG	5	3	1	6	7	5	9	12/93	Rose et al.	424	10	

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JN	JH	00	0	5	1	5	9	2	9/05/00	WO	A61K	31/14		

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

JN	JN	<del>Benjamin et al., "Naltrexone shortened opioid detoxification with buprenorphine"; Drug and Alcohol Dependence (1999) Vol 56 pp. 181-190</del>											
JN	JK	Vaccarino et al., "Endogenous Opiates: 1999"; Peptides 21 (2000) pp. 1975-2034.											
JN	JL	Wang et al., "Inverse Agonists and neutral antagonists at $\mu$ -opioid receptor (MOR): possible role of basal receptor signaling in narcotic dependence"; J. Neurochemistry (2001) Vol 77, pp. 1590-1600.											
JN	JM	Way et al., "Responsivity to Naloxone during Morphine Dependence"; Annals New York Academy of Sciences, pp. 252-261.											
JN	JN	Weinberg et al., "Sublingual absorption of selected opioid analgesics"; Clin Pharm Thera (1988) Vol 44, No 3, pp. 335-342.											
JN	JO	Wells, et al., "In vivo Pharmacological Characterization of SBRI 9409, a Nonpeptidic Opioid $\mu$ -Agonist/ $\delta$ -Antagonist that Produces Limited Antinociceptive Tolerance and Attenuates Morphine Physical Dependence"; J. Pharm and Exper Thera (2001) Vol 297, No 2, pp. 597-605											
JN	JP	Wodak, Alex, "Drug Treatment for Opioid Dependence"; Australian Prescriber (2001) Vol 24, No 1, pp. 4-6.											
JN	JO	Wright et al., "Acute physical dependence in Humans; repeated naloxone-precipitated withdrawal after a single-dose of methadone"; Drug and Alcohol Dependence (1991) Vol 27, pp. 139-148.											
JN	JR	Zhu et al., "Naltrexone-precipitated morphine withdrawal in infant rat is attenuated by acute administration of NOS inhibitors but not NMDA receptor antagonists"; Psychopharmacology (2000) Vol 150, pp. 325-336.											

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
JR	KA 5 3 1 7 0 2 2	5/94	Borsodi et al.	514	282		
JR	KB 5 3 2 1 0 1 2	6/94	Mayer et al.	514	25		
JR	KG 5 3 2 4 3 5 1	06/28/1994	Oshlak et al.	106	153		
JR	KE 5 3 3 6 6 9 1	08/09/1994	Raffa et al.	514	629		
JR	KE 5 3 5 2 6 8 0	10/94	Portoghese et al.	514	279		
JR	KF 5 3 5 2 6 8 3	10/94	Mayer et al.	514	289		
JR	KG 5 3 5 6 4 6 7	10/18/1994	Oshlak et al.	106	153		
<b>FOREIGN PATENT DOCUMENTS</b>							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
JR	KH 0 1 5 8 4 5 1	08/19/2001	WO (A1)	A61K	31/485		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
KI	<del>Han et al., "Mucoadhesive buccal disks for novel nalbuphine prodrug controlled delivery; effect of formulation variable on drug release and mucoadhesive performance"; International J. Pharm (1999) Vol 177, pp. 201-209.</del>						
KJ	<del>Handal et al., "Naloxone"; Annals of Emergency Medicine (1983) Vol 12:7, pp. 438-445</del>						
KK	<del>Harris et al., "Buprenorphine and Naloxone co-administration in opiate dependent patients stabilized on sublingual buprenorphine"; Drug and Alcohol Dependence (2000) Vol 61, pp. 85-94.</del>						
KL	<del>Hawkes et al., "Effect of enteric-release formulation of naloxone on intestinal transit in volunteers taking codeine"; Aliment Pharm Ther (2001) Vol 15, pp. 625-630.</del>						
KM	<del>Högger et al., "Comparison of tilidine/naloxone, tramadol and buprenorphine in experimental pain: a double-blind randomized crossover study in healthy human volunteers"; International J. Clin Pharm and Thera (1999) Vol 37, No 8, pp. 377-385</del>						
KN	<del>Budd, Keith, "Clinical Use of Opioid Antagonists"; Bailliere's Clinical Anesthesiology (1987) Vol 1, No 4, pp. 993-1011.</del>						
KO	<del>Grain et al., "Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence</del>						
KP	<del>Hoyes et al., "The Pharmacology of TR5109, a new Narcotic Agonist/Antagonist Analgesic"; NIDA Research (1979) pp. 99-105.</del>						
KQ	<del>Leeling et al., "Disposition and metabolism of codephone in the rat, dog, and man"; Drug Metabolism and Disposition (1982) Vol 10, No 6, pp 649-653.</del>						
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JR	LA	5 3 5 6 9 0 0	10/94	Bihari et al.	514	282			
JR	LB	5 3 7 6 6 6 2	12/94	Ockert	514	282			
JR	LC	3 5 4 1 0 0 5	11/17/1970	Strathmann, et al.	210	19			
JR	LD	5 4 1 1 7 4 5	05/02/1995	Oshlack et al.	424	456			
JR	LE	5 4 2 6 1 1 2	06/95	Zagon et al.	514	282			
JR	LF	3 5 4 1 0 0 6	11/17/1970	Bixler, et al.	210	23			
JR	LG	5 4 5 7 2 0 8	10/95	Portoghese et al.	546	35			
<b>FOREIGN PATENT DOCUMENTS</b>									
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION			
						YES	NO		
JR	LH	0 8 8 0 3 5 2	02/03/1998	EP (B1)	A61K	31/485	x		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>									
/	LI	Amass et al., "Efficacy of daily and alternate-day dosing regimens with the combination buprenorphine-naloxone tablet"; Drug and Alcohol Dependence (2000) Vol 58, pp. 143-152.							
/	LJ	Hassain et al., "Duccal and oral bioavailability of naloxone and naltrexone in rats"; (1987) Vol 36, pp. 127-130.							
/	LK	Jasinski et al., "The human pharmacology and abuse potential of N-allylnoroxymorphone naloxone"; J. Pharm and Exper Thera (1967) Vol 157, No 2, pp. 420-426.							
/	LM	Jones et al., "Nalmefene: blockade of intravenous morphine challenge effects in opioid abusers in humans"; Drug and Alcohol Dependence (2000) Vol 60, pp. 29-37.							
/	LN	Kann et al., "Clinical Characteristics of Naloxone-Precipitated Withdrawal in Human Opioid-Dependent Subjects"; J Pharma and Exper Thera (1992) Vol 260, No. 1, pp. 355-363.							
/	LO	King et al., "Naltrexone Biotransformation and Incidence of Subjective Side Effects: A Preliminary Study"; Alcoholism: Clin and Exper Res (1997) Vol 21, No 5, pp. 906-909.							
/	LP	Kogen et al., "Estimation of the Systemic Availability and Other Pharmacokinetic Parameters of Naltrexone in Man after Acute and Chronic Oral Administration"; Res. Comm. In Chem. Path. And Pharm (1977) Vol 18, No. 1, pp. 29-34.							
/	LQ	Kosten, Thomas R., M.D., "Buprenorphine for Benzodiazepine-Abusing Heroin Addicts"; Amer J of Psychiatry (1994) Vol 1, p 151.							
/	LR	Kosten et al., "Opioid antagonist challenges in buprenorphine maintained patients"; Drug and Alcohol Dependence (1990) Vol 25, OO. 73-78.							
/	LS	Kurland et al., "Naloxone and the Narcotic Abuser: A Controlled Study of Partial Blockade"; Inter. J. of the Addictions (1974) Vol 9, No 5, pp. 663-672.							
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JR	MA	5	4	6	0	8	2	6		10/24/1995	Merrill et al.	424	470	
JR	MB	5	4	7	2	7	1	2		12/05/1995	Oshlack et al.	424	480	
JR	MC	5	4	7	2	9	4	3		12/95	Crain et al.	514	12	
JR	MD	5	4	7	8	5	7	7		12/26/1995	Sackler et al.	424	489	
JR	ME	5	4	8	6	3	6	2		1/96	Kitchell et al.	424	426	
JR	MF	5	5	0	0	2	2	7		03/19/1996	Oshlack et al.	424	476	

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														YES	NO
	MG														

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	MR	Lee et al., "Nalbuphine Coadministered with Morphine Prevents Tolerance and Dependence"; Anesth Analg (1992) Vol 84, pp.810-815
	MI	Lehman, et al., "Influence of Naloxone on the Postoperative Analgesic and Respiratory effects of Buprenorphine"; Eur. J. Clin Pharm (1988) Vol 34, pp. 343-352.
JR	MJ	Levine et al., "Potentiation of Pentazocine Analgesia by Low-dose Naloxone"; J Clin Invest (1988) Vol 82, pp. 1574-1577.
	MR	Loimer et al., "Combined Naloxone/Methadone Preparations for Opiate Substitution Therapy"; J. of Substance Abuse Treatment (1991) Vol 8, pp. 157-160.
	ML	Martin et al. "Bioavailability Investigation of a New Tilidine/Naloxone Liquid Formulation Compared to a Reference Formulation"; Arzneim-Forsch/Drug Res. (1999) Vol 49, pp. 599-607.
	MM	Martin et al., "Demonstration of Tolerance to and Physical Dependence on N-allylnormorphine (Nalorphine)"; J. Of Pharm and Exper Thera (1965) Vol 150, No 3. Pp. 437-442.
	MN	Mendelson et al., "Buprenorphine and naloxone combinations: the effects of three dose ratios in morphine stabilized, opiate-dependent volunteers"; Psychopharmacology (1999) Vol 141, pp. 37-46.
	MO	Mendelson et al., "Buprenorphine and naloxone Interactions in Methadone Maintenance Patients"; Society of Biological Psychiatry (1997) Vol 41, pp. 1095-1101.
	MP	Nutt et al., "Methadone-naloxone mixture for use in methadone maintenance programs"; Clin Pharm and Ther. Vol 15, No 2, pp 156-166

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<i>JE</i> <i>JE</i> <i>JE</i> <i>JE</i> <i>JE</i>	NA	5 5 0 2 0 5 8	3/96	Mayer et al.	514	289			
	NB	5 5 0 8 0 4 2	04/16/1996	Oshlack et al.	424	468			
	NC	5 5 0 8 0 4 3	04/16/1996	Krishnamurthy	424	484			
	ND	5 5 1 2 5 7 8	4/96	Crain et al.	514	282			
	NE	5 5 1 4 6 8 0	5/96	Weber et al.	514	249			
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							YES	NO	
	NF								
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)									
	NG	Parvatikar et al., "Methadone-naloxone in combination for the Treatment of Heroin Addicts", Clin. Pharm and Ther., Vol 14, No. 6, pp 941-948.							
	NH	Parvatikar et al., "Naloxone-Methadone Combination for the Treatment of Opiate Dependence"; Missouri Institute of Psychiatry, pp. 1350-1354.							
	NI	Pitts et al., "Antinociceptive and Response Rate-Altering Effects of Kappa Opioid Agonists, Spiradoline, Enadoline and U69,593, Alone and in Combination with Opioid Antagonists in Squirrel Monkeys"; J of Pharm and Exper Thera (1994) Vol 271, No 3, pp. 1501-1508.							
	NJ	Preston et al., "Buprenorphine and Naloxone alone and in combination in Opioid-dependant Humans"; Psychopharmacology (1988), Vol 94, pp. 484-490.							
	NK	Preston et al., "Differential Naltrexone Antagonism of Hydromorphone and Pentazocine Effects in Human Volunteers"; J of Pharm and Exper Thera (1993) Vol 264, No 2 pp. 813-823.							
	NL	Preston et al., "Effects of Sublingually given naloxone in Opioid-dependant human volunteers"; Drug and Alcohol Dependence (1990) Vol 25, pp. 27-34.							
	NM	Bigelow et al., "Abuse Liability and Assessment of Buprenorphine-Naloxone Combinations"; Dept of Psychiatry and Behavioral Sciences, The Johns Hopkins University School of Medicine, pp. 145-149.							
	NN	Wikler et al., "N-Allylnormorphine: Effects of single dose and Precipitation of Acute "Abstinence Syndromes" during addiction to morphine, methadone or heroin in man (post addicts)"; N-Allylnormorphine During Narcotic Addiction (1953) pp. 8-20.							
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JR	OA	5	5	3	4	4	9	2	7/96	Aston et al.	514	608	
JR	OB	5	5	4	9	9	1	2	08/27/1996	Oshlack et al.	424	468	
JR	OC	5	5	5	2	4	2	2	09/03/1996	Gauthier et al.	514	368	
JR	OD	5	5	5	6	8	3	8	9/96	Mayer et al.	514	25	
JR	OE	5	5	7	4	0	5	2	11/96	Rose et al.	514	343	

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													YES	NO
	OF													

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

- OG ☒ Zaks et al., "Naloxone Treatment of Opiate Dependence"; JAMA (1971) Vol 215, No 13, pp. 2108-2110.
- OH ☒ Barton et al., "Intranasal Administration of Naloxone by Paramedics"; Prehospital Emergency Care (2002) Vol 6, No 1, pp. 54-58.
- OI ☒ Blachy, Paul, H., M.D., "Naloxone in Opiate Addiction"; Current Psychiatric Therapies (1976) pp. 209-213.
- OJ ☒ Bashaw et al., "Relative bioavailability of controlled-release oral morphine sulfate during naltrexone blockade"; Inter J of Clin Pharm and Thera (1995) Vol 33, No 9, 524-529.
- OK ☒ Jasinski, D.R., "Assessment of the Abuse Potential of Morphine-like Drugs (Methods Used in Man); Drug Addiction (1977) pp. 197-258.
- OL ☒ Johnson et al., "Buprenorphine and Naloxone for Heroin Dependence"; Substance Use Disorders (2000) pp. 519-526.
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EXAMINER

Jeffrey E. Russel

DATE CONSIDERED

January 25, 2005

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1134CON		SERIAL NO.: 10747,865	
<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (Use several sheets if necessary)				APPLICANT(S): Benjamin OSHLACK et al.			
				FILING DATE: December 29, 2003		GROUP: 1614	
<b>U.S. PATENT DOCUMENTS</b>							
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
RA	5 6 5 6 2 9 5	08/12/1997	Oshalck et al.	424	468		
RB	5 6 7 0 1 7 2	09/23/1997	Buxton et al.	424	495		
RC	5 6 7 2 3 6 0	09/30/1997	Sackler et al.	424	490		
RD	5 6 8 1 5 8 5	10/28/1997	Oshlack et al.	424	494		
RE	5 7 6 3 4 5 2	06/09/1998	Miller et al.	514	282		
RF	5 7 6 7 1 2 5	06/98	Crain et al.	514	282		
RG	5 7 8 0 4 7 9	07/14/1998	Kim	514	282		
RH	5 7 6 7 1 2 5	06/16/1988	Crain, et al.	514	282		
RI	6 0 9 6 7 5 6	08/01/2000	Crain, et al.	514	282		
RJ	6 1 9 4 3 8 2	02/27/01	Crain, et al.	514	2		
RK	6 3 6 2 1 9 4	03/26/2002	Crain, et al.	514	285		
RL	6 3 9 5 7 0 5	05/28/2002	Crain, et al.	514	2		
RM	20 01 00 06 9 6 7	07/05/2001	Crain, et al.	514	253.04		
RN	20 01 00 18 4 1 3	08/30/2001	Crain, et al.	514	2		
<b>FOREIGN PATENT DOCUMENTS</b>							
DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
					YES	NO	
RO							
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
RP	Ciccocioppo et al., "Effect of Nociceptin/orphanin FQ on the Rewarding Properties of Morphine"; Eur. J Pharmacol (2000) Vol 404, pp. 153-159.						
RQ	<del>Physician's Desk Reference (2001) see Revia pp. 1146-1149 and Oxycontin, pp. 2697-2701</del>						
RR							
RS							
EXAMINER <i>Jeffrey E. Russell</i>				DATE CONSIDERED <i>January 25, 2005</i>			
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